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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,250	08/21/2001	Wenbin Dang	GPT-029.01	6514

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EXAMINER
STILLER, KARL J

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/17/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/934,250	Applicant(s) DANG ET AL.	
	Examiner Karl Stiller	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-41, drawn to a flowable pharmaceutical composition or kit, comprising a biocompatible oil and a sparingly soluble pharmaceutically acceptable salt of an analgesic agent, diversely classified in Class 514, for example, Subclasses 182, 282, 392, 570, 626, 678, 690, etc.

II. Claims 42-56, drawn to a method of treating a disease or condition in a subject, comprising administering a composition comprising a biocompatible oil and a therapeutically effective amount of a pharmaceutically acceptable salt of an analgesic agent which is sparingly soluble in a biocompatible oil, diversely classified in Class 514, for example, Subclasses 182, 282, 392, 570, 626, 678, 690, etc.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as a

pharmaceutically acceptable salt of an analgesic agent, for example, in an aqueous vehicle.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

If applicants elect the invention of Group I, applicants are further required to make the following species election:

Claims 1-41 are generic to a plurality of disclosed patentably distinct species comprising pharmaceutically acceptable salts of analgesic agents and biocompatible oils. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, which is a single disclosed pharmaceutically acceptable analgesic agent salt and a single disclosed biocompatible oil, even though this requirement is traversed.

If applicants elect the invention of Group II, applicants are further required to make the following species election:

Claims 42-56 are generic to a plurality of disclosed patentably distinct species comprising pharmaceutically acceptable salts of analgesic agents, biocompatible oils and diseases or conditions to be treated. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, which is a single disclosed pharmaceutically acceptable analgesic agent salt, a single disclosed pharmaceutically acceptable oil, and

a single disclosed disease or condition to be treated, even though this requirement is traversed.

The search for all species of individual agents useful in the products and methods herein presents an undue burden on the office due to their structural dissimilarities. Note, for example, that ibuprofen sodium is classified in Class 514, Subclass 570, morphine sulfate is classified in Class 514, Subclass 282, clonidine hydrochloride is classified in Class 514, Subclass 293, and lidocaine hydrochloride is classified in Class 514, Subclass 626. The biocompatible oils useful in the composition herein also present an undue burden on the office due to their structural dissimilarities. Note, for example, that cholesterol is classified in Class 514, Subclass 182, vitamin K is classified in Class 514, subclass 678, and coenzyme Q is classified in Class 514, Subclass 690.

Please also note that the search is not limited to the patent files.

Therefore, due to the structural diversity of active compounds useful in the composition herein and their corresponding diverse classification, the search for all species of pharmaceutically acceptable analgesic agent salts and biocompatible oils would present an undue burden on the office.

The search for all species of diseases or conditions treatable with a composition herein presents an undue burden on the office due to their separate and distinct fields of search. Note that the search is not limited to the patent files. The claims are drawn to the treatment of many disease states or conditions, for example, tinnitus and pain. The search field for tinnitus and pain differ. Tinnitus is routinely treated by treating the

underlying disease or condition of which tinnitus presents as a symptom. Common causes of tinnitus include anxiety, alcohol or drug abuse, ear infection, and cardiovascular disease. The routine treatment of these underlying diseases or conditions would not obviate a method of treating pain. Pain is routinely treated by administering analgesics such as non-steroidal anti-inflammatory agents, or opioid analgesics, and the application of heat or cold, whereas tinnitus routinely is not. In fact, the administration of many medications can actually cause tinnitus. For example, the administration of salicylates (most notably aspirin) in a method of treating pain can cause tinnitus.

Therefore, due to the characteristic diversity of medical disorders within the claims and their treatment within the art, the search for all species of individual disorders would present an undue burden on the office.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Kingsly Taft on December 10, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
December 11, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600